

SUPPORT FOR THE AMENDMENTS

The amendments to the pending claims and newly-added Claims 95-103 are supported by the specification at, *inter alia*, page 14, lines 10-18. Accordingly, no new matter is believed to have been added to the present application by the amendments submitted above.

REMARKS

Claims 69-103 are pending, upon entry of the amendment submitted above.

Favorable reconsideration is respectfully requested.

Applicants would like to thank Examiner Bertoglio for helpful comments in the Office Action.

The present invention includes a mammalian non-human female animal having a complete depletion of ovarian primordial follicles and at least one characteristic selected from the group consisting of depletion of ovarian follicles, irregular ovarian cyclicity, cessation of estrous cyclicity, elevated FSH levels, erratic ovarian 17β -estradiol levels, loss of bone mineral density, and reduced ovarian weight, wherein the animal has been administered 4-vinylcyclohexene diepoxide (hereinafter referred to as "VCD") at a dosage of 100 mg/kg/day to 720 mg/kg/day. See Claim 69.

The rejection of Claim 69 under 35 U.S.C. §112, first paragraph, is respectfully traversed. The specification provides a description a mammalian non-human female animal having a complete depletion of ovarian primordial follicles as specified in Claim 69.

A general purpose of the present invention is to provide an animal model suitable as a model of human perimenopause and/or menopause. See the specification at page 7, lines 2-3. The animal is defined broadly as "having at least a partial depletion of ovarian follicles" obtained by administering VCD. See the specification at page 7, lines 12-16. Of course, "at least partial depletion" embraces complete depletion.

In fact, complete depletion of ovarian primordial follicles is described in Example 1 beginning at page 20 of the specification. In the experiment described therein, animals were treated with VCD at a dose of 160 mg/kg/day-- i.e., within the range specified in Claim 69.

The specification reports:

There were no primordial follicles and primary, secondary and antral follicles were 0.5%, 0.7%, and 2.6% of control values respectively (Figure 2B). [Emphasis added.]

Page 21 of the specification states:

The optimal concentration of VCD for primordial follicle loss (lowest amount, shortest time) was determined to be 160 mg/kg/day, injected 1x daily (*resulting in complete loss of primordial follicles*). [Emphasis added.]

In view of the foregoing, the specification clearly shows that administering VCD as claimed produces complete depletion of ovarian primordial follicles as specified in Claim 69.

In view of the foregoing, Claim 69 is not directed to new matter. Rather, the subject matter of that claim was described in the specification at the time of filing. Accordingly, withdraw of this ground of rejection is respectfully requested.

The rejection of Claims 83-94 under 35 U.S.C. §112, second paragraph, is believed to be obviated by the amendments submitted above. The claims have been amended to address the issues raised by the Examiner. Claims 88 and 93 specify a narrower range of administered VCD. In view of the amendments, withdrawal of this ground of rejection is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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